In Re:

Digitek

Paul Galea

December 9, 2009

Confidential – Subject to Further Confidentiality Review

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EXHIBIT C-4

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

- - -

IN RE: DIGITEK® PRODUCTS LIABILITY LITIGATION MDL NO. 1968

THIS DOCUMENT RELATES TO
ALL CASES

CONFIDENTIAL -
SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

- - -

Wednesday, December 9, 2009

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Videotaped deposition of PAUL GALEA, held at HARRIS BEACH, PLLC, 100 Wall Street, New York, New York, commencing at approximately 9:50 a.m., before Rosemary Locklear, a Registered Professional Reporter, Certified Realtime Reporter, Certified Court Reporter (NJ) and Notary Public.

GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph | 971.591.5672 Fax
deps@golkow.com

APPEARANCES:

BLIZZARD McCARTHY & NABERS, LLP
BY: EDWARD F. BLIZZARD, ESQUIRE
eblizzard@blizzardlaw.com
BY: HOLLY W. GIBSON, ESQUIRE
hgibson@blizzardlaw.com
Lyric Centre, Suite 1710
440 Louisiana
Houston, Texas 77002-1689
(713) 581-8451
Appearing on behalf of Plaintiffs

THE MILLER FIRM, LLC
BY: PETER A. MILLER, ESQUIRE
pmiller@doctoratlaw.com
The Sherman Building
108 Railroad Avenue
Orange, Virginia 22960
(540) 672-4224
Appearing on behalf of Plaintiffs in Pennsylvania

MOTLEY RICE, LLC
BY: MEGHAN JOHNSON CARTER, ESQUIRE
mjohnson@motleyrice.com
28 Bridgeside Boulevard
Mount Pleasant, South Carolina 29464
(843) 216-9000
Co-Lead Counsel for the Plaintiffs' Steering Committee

SANFORD BARLOW, LLP
BY: ANTHONY COVENY, ESQUIRE
(via telephone)
1500 McGowen Street, Suite 250
Houston, Texas 77004
(713) 524-6677
Appearing on behalf of the Plaintiffs

APPEARANCES: (Continued)

TUCKER ELLIS & WEST, LLP
BY: MICHAEL ANDERTON, ESQUIRE
manderton@tuckerellis.com
BY: EDWARD E. TABER, ESQUIRE
etaber@tuckerellis.com
1150 Huntington Building
925 Euclid Avenue
Cleveland, Ohio 44115-1475
(216) 592-5000
Appearing on behalf of the Defendant Actavis

ALLEN GUTHRIE & THOMAS, PLLC
BY: ZACKARY B. MAZEY, ESQUIRE
zbmazey@agmtlaw.com
500 Lee Street, East, Suite 800
Charleston, West Virginia 25301
(304) 345-7250
Appearing on behalf of the Defendant Mylan Actavis in West Virginia

SHOOK, HARDY & BACON, LLP
BY: SEAN LEE, ESQUIRE
slee@shb.com
1155 F Street, N.W., Suite 200
Washington, DC 20004-1305
(202) 783-8400
Appearing on behalf of the Defendant Mylan Pharmaceuticals

ALSO PRESENT:

CATHERINE SMALFUS, Video Operator

Q. Was that at the request of the company or had you been requesting to transfer to the U.S.?

A. It -- it was a bit of both, I could say.

Q. What was -- as you were informed, what was the reason that the company requested it, that you transfer to Actavis Totowa?

A. The initial reason, I was doing an assessment and helping out in the harmonization of the group's corporate manual, and that was basically the main reason.

Q. All right. Well, let's break that into two parts.

What was the assessment that you believe that you were -- that you came here to work on? Assessment of what?

A. Basically, I came to make an assessment of Actavis Totowa, L.L.C.

Q. Overall assessment of the QA Department?

A. No. In general of the company

from a -- from a GMP perspective.

Q. Would you agree with me that there was some serious GMP issues in October of '07 at Actavis Totowa?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: How do you define serious?

BY MR. MILLER:

Q. Serious? Well, there could have been some GMP problems that would have been, gosh, this is minor, we either need to fix it or we don't need to fix it, or there are some issues where if we don't fix it, then we might be shut down or someone might get hurt.

MR. ANDERTON: Objection.

BY MR. MILLER:

Q. It's okay to answer.

MR. ANDERTON: You may answer.

THE WITNESS: When I first went there, that was not really the scope of my assessment. My assessment was to look at the company and -- and, basically, have a look at

the operation.
BY MR. MILLER:
Q. Have a look at the operation, but through the lens of GMP and what the status of the company applying and using GMP. Is that fair?
A. Yes, that is fair to say.
Q. Who else was on the assessment team, or was it just you?
A. At this point it was me.
Q. Arriving in October of 2007 to do an assessment of the GMP, who were you reporting to?
A. I was still reporting to -- to Actavis, Limited.
Q. Okay. We have -- excuse me, sir.
MR. MILLER: We have someone just checked in on the phone line. If that is correct, would you please identify yourself.
MR. COVENY: Anthony Coveny with Shelly Sanford's office.
MR. MILLER: Okay. Well, we've gotten started. If you would, please, put it on

Q. Just got a call in Malta and said go to Actavis Totowa and make an assessment of their GMP program?

A. Yes. I would say that is correct.

Q. You agreed with me earlier that there are serious issues at the -- with GMP at Actavis Totowa.

Did you have that understanding prior to your assessment?

MR. ANDERTON: Objection.

That totally mischaracterizes the witness's testimony.

MR. MILLER: Well --

THE WITNESS: I -- I did not agree that there were serious issues.

BY MR. MILLER:

Q. Okay. I'll ask -- all right.

Let me ask this: Do you believe there were serious issues with the GMP procedures at Actavis Totowa prior to your arrival in October of 2007?

MR. ANDERTON: Objection.

I instruct the witness not to

MR. ANDERTON: Okay.

BY MR. MILLER:

Q. What was your mental understanding of the status of the GMP protocol procedures at Actavis Totowa prior to your arrival in October of 2007?

A. I had no real understanding of what I was going to be assessing.

Q. Did you have a mental understanding prior to October of 2007 of things are going really good, I'm going there to learn how to do GMP right?

A. As I already said, I had no understanding of the company before the time I went there.

Q. How long did your GMP assessment last after your arrival? How long did you continue in that role?

A. I was there from -- the initial visit was from the 2nd of February, I think, to around about the 9th. A week in total.

Q. So you continued an assessment from October of '07 until February of '09.

Q. Phone?

And what did she inform you on that phone call that your mission was going to be on your trip?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: She asked me if I would be willing to go over to the U.S. to make an assessment of Actavis Totowa, L.L.C.

BY MR. MILLER:

Q. And did she indicate one way or the other what she thought you were going to find when you arrived?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: No.

BY MR. MILLER:

Q. Was any communication between you and her done in -- via E-mail or writing or any other form?

A. We communicated by phone.

Q. Did you communicate with Scott Talbot prior to your arrival?

A. No.

A. I cannot say that it is there until today. Today there could be just computer logs.

Q. Who is the keeper of the logbook for contacts?

A. There isn't an actual contact logbook. It's a complaint logbook. And they would make comments if they did actually manage to contact the -- the person making the complaint.

Q. Okay. That logbook, where was it physically held back when you maintained this title in 2007?

A. We keep those in a documentation room.

Q. Okay. And then how often would you review the logbook or the computer spreadsheets?

A. Can you rephrase that?

Q. Certainly.

What would be, as your title of quality system director, what would be your involvement of the complaints?

Once Bernard or Barbara had

contacted the customers that had initiated the complaint, what involvement, if any, did you have in the complaints?

A. My involvement would be to -- to look at basically the information that they had gathered and any reports they would have subsequently made in view of that information with respect to the particular complaint.

Q. Okay. And then would you condense that information or would you put it in some other format to present to someone else inside the company?

A. No.

Q. So the -- your -- felt like your job title as quality systems director, then, was to have the complaints maintained in a logbook and a computer, but they didn't go anywhere from there?

A. Can you rephrase that?

Q. Did you have any obligation to pass that information on to anyone else outside of your department?

A. That information was open to

the site head of quality and to the QA director.

Q. All right. Open to me means that he can go grab that logbook and look at it if he wants to or he can open up that computer spreadsheet and read that if he wants to.

But my question is, was there any obligation on your part to take that information and physically move it forward to some other entity besides your department, quality systems, at that time in 2007?

A. We definitely would notify the site head of quality and the QA director of complaints that we received.

Q. How did you notify them?

A. Verbally, most of the time, because they were, you know, in the same office area, basically.

Q. So it was just a matter of saying, hey, I've got this complaint and this is what the person said, you would inform them of that, but there was no written report that you would put together

of complaints.

A. Yes. There are written reports. And, typically, you are contacting -- contacting these people because the QA director would be involved in resolving that complaint.

Q. But did your office generate any of those reports?

A. My people would generate those reports.

Q. What would those reports be called?

A. Complaint report. The report is more of like a -- typically a form --

Q. Okay.

A. -- with the various information to it.

Q. And was there an SOP that governed how often that report had to be generated or who that report went to?

A. Definitely the SOP governed that a report would be generated with each complaint. Whether conclusive or inconclusive or whatever information we

had.

And the second part of the question was?

Q. Gosh, I forgot myself. The second part -- I guess, we'll make a new second part.

Who would those reports go to? Did the SOP indicate who the report went to?

A. That I cannot remember.

Q. Well, I'm not asking you to remember specifically by name or title who it went to, but did the SOP direct that there was a particular receiver, someone who was going to get that report?

A. The report would be viewed, as far as I can recall, by either the site head of quality or the QA director. They had access to all those reports also.

Q. So October of '07 you're quality systems director. How long did you maintain that title?

A. I maintained that title until around about June of 2008.

Q. And what's your title in June

as a result there is no assurance that many drug products manufactured and released into interstate commerce by your firm have the identity, strength, quality and purity that they purport to possess."

Q. Okay. And, sir, would you agree with me that that is very specific, that it's not a manufacturing problem, but it's a quality control, GMP problem?

MR. ANDERTON: Objection.

BY MR. MILLER:

Q. It's okay to answer.

MR. ANDERTON: You may answer.

THE WITNESS: From what it is written here, they are saying quality control unit, so I do agree that they mentioned quality control --

BY MR. MILLER:

Q. Okay.

A. -- in this context.

Q. Thank you very much.

And then let's turn the page to Number 2 of the revised warning letter. And all I need you to do is read the first sentence,

sir, if you would, of Number 2.

MR. ANDERTON: Do you want to just indicate a Bates page number, Pete, for the record, please.

MR. MILLER: Certainly.

This is Page 2 of the warning letter, which is Actavis 0028243.

THE WITNESS: "Our investigators observed that laboratory notebooks did not include all raw test data generated during testing and that analysts do not always document the preparation and testing of samples in their notebooks at the time they are done."

BY MR. MILLER:

Q. So you would agree with me that's a violation of the cGMP; correct?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: This is what the auditor report. I do not know if or what the company or the firm actually responded back to this.

BY MR. MILLER:

Q. Well, I'm not asking what they

responded back. I'm just -- as someone who's there to do an assessment of a pharmaceutical lab's GMP procedures, you would agree that if the FDA writes you up for the investigators observed that laboratory notebooks did not include all raw test data -- I won't continue to read the whole thing -- but you would agree that they were writing up a violation of GMP?

MR. ANDERTON: Objection.

BY MR. MILLER:

Q. It's okay to answer.

MR. ANDERTON: You may answer.

THE WITNESS: If you look at that statement as written, yes, I would agree with you.

BY MR. MILLER:

Q. Okay. And you agree that that's not on the manufacturing side of the house, that's a quality control side of the house.

A. Once again, it's the lab, which is mentioned.

Q. Okay. Let's take a look at Finding Number 3.

And if you would be so kind, this is Actavis 008244, Page 3 of the FDA warning letter, would you read the first sentence of Number 3, please, sir.

A. "There was a failure to check for accuracy the inputs to and outputs from the 'Total Chrom Data Acquisition System,' which is used to run your firm's HPLC instruments during analysis of drug products."

Q. And as that is written by the FDA in the warning letter, you would agree that that's a violation of the cGMP?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: As that is written, yes.

BY MR. MILLER:

Q. And you would agree that that's a quality-control side of the house and not the manufacturing side of the house.

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Yes.

BY MR. MILLER:

Q. Okay. Let's take a look at Number 4. And this is same page, if you would read, first sentence of Finding Number 4, sir.

A. "Our investigators observed numerous instances where your firm's quality control unit either ignored or failed to recognize that some tablets did not meet in-process specifications."

Q. And you would agree with me that that -- the way that's written, that's a violation of the GMP.

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: As written, yes.

Again, I state that I do not know what the firm answered back.

BY MR. MILLER:

Q. And you would agree that there -- this is not the manufacturing side of the pharmaceutical industry, this is the

quality-control side.

A. That's exactly what is written.

Q. Okay. Thank you.

Let's take a look at Finding Number 5. Would you read the first line of Finding Number 5, Actavis 0028245, please, sir.

A. 5?

Q. Yes.

A. Okay. "Your firm lacked adequate procedures for conducting bulk product holding time studies."

Q. Okay. Now, would you agree with me this is a quality-control issue and not a manufacturing aspect?

MR. ANDERTON: Objection. Objection. Sorry, Pete.

You may answer.

THE WITNESS: I believe that bulk product holding time studies are more of a QA than a QC issue. QC is responsible for testing.

BY MR. MILLER:

Q. Okay. QC is involved with testing. And QA is involved with what?

A. QA is more looking that GMPs

are being followed.
Q. Okay. Don't GMPs need to be followed in testing as well?
A. Definitely.
Q. Definitely. Okay.
Well, then if we're doing -- GMPs are applied in both QC and QA, how would you distinguish QA from QC?
A. I would distinguish because, typically, it would be QA who would set up a program for bulk holding time studies, and QC would be performing tests --
Q. Okay.
A. -- on those materials that resulted from the study.
Q. But all involve the GMP.
A. Definitely.
Q. Okay. So let's take a look at Number 6, if you would be so kind.
A. "Your firm failed to identify and control rejected in-process materials to prevent their use in manufacturing or processing operations."
Q. Now, I'm not 100 percent sure,

but I think this goes to the manufacturing side of the house.

MR. ANDERTON: Objection.

BY MR. MILLER:

Q. Do you agree? Or is this a QA/QC issue?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: I would say this is strictly a QA --

BY MR. MILLER:

Q. QA. Okay.

A. -- function.

Q. And, again, follows the guidelines of the GMP?

A. Yes.

Q. Okay. Now, read Number 7, please.

A. "Your firm's cleaning validation studies were found to be inadequate and, as a result, there was no assurance that equipment is adequately cleaned between the manufacture of different drug products [21 CFR 211.67],"

and then there's an example.

Q. Okay. Now, is that a quality control, quality assurance or manufacturing issue?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: This to me would fall under the umbrella of tech services and QA.

BY MR. MILLER:

Q. Okay. QA.

Let's take a look at the next page, Actavis 0028246. And, specifically, the next finding, which would be Finding Number 8, if you would read that first sentence.

A. "Master and batch production and control records were found to be deficient in that they did not include complete procedures for documenting the collection of samples."

Q. And, now, do you believe that to be a QA, a QC or a manufacturing issue?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: QA.

BY MR. MILLER:

Q. QA. Okay.

All right. Only two to go, sir.

Let's take a look at the FDA's Finding Number 9 in their warning letter of February '07.

Would you read that first sentence, please.

A. "Equipment used in the manufacture of," blanked out, "and other drug products was not adequately qualified."

Q. Now, is qualification of manufacturing equipment, is that a manufacturing issue or is that a QA/QC issue?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: It's a tech services/QA issue.

BY MR. MILLER:

Q. All right. Let's take a look at Number 10. This is the tenth numbered finding of the warning letter from the

FDA.

If you would take a look at that and read the first sentence, sir.

A. "There were failures to establish and follow written procedures for maintenance of manufacturing equipment."

Q. Okay. Now, is this a manufacturing issue specifically or is this QA/QC?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: As the phrase reads, or the observation reads, it is a maintenance issue, not following written procedures.

BY MR. MILLER:

Q. Okay. So that's on the manufacturing side of the house.

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Engineering worked closely together with manufacturing, but they are distinct groups, typically.

BY MR. MILLER:

Q. But it's not a GMP issue.

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: If by GMP you understand quality group, the failure to follow written procedures in this case did not stand from the quality group, but from the maintenance group.

BY MR. MILLER:

Q. Okay. But you did agree that nine of the ten findings fell under the quality group.

MR. ANDERTON: Objection; mischaracterizes his testimony.

You may answer.

THE WITNESS: I would say that it was shared responsibility between the quality group and to some extent other groups.

BY MR. MILLER:

Q. Okay. Would you agree that the overall finding from the FDA, albeit you didn't read this letter, but you had a conversation regarding it, is the quality group having issues with GMP?

MR. ANDERTON: Objection.

BY MR. MILLER:

Q. It's okay to answer.

MR. ANDERTON: You may answer.

THE WITNESS: Yes. From -- from what this letter says and from the discussions I had, it is clearly indicated that the quality group was responsible for this.

MR. MILLER: I've been informed we have a few minutes left. We're going to take a break.

THE WITNESS: Okay.

VIDEO OPERATOR: We are now going off the record.

This is the end of Videotape Number 1.

The time is 11:10.

(Recess, 11:10-11:30 a.m.)

VIDEO OPERATOR: We are now back on the record.

This is the beginning of Videotape Number 2.

The time is 11:30.

MR. MILLER: Before we get started,

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: No.

BY MR. MILLER:

Q. And, in fact, the GMP at Actavis Totowa, the procedures of GMP as used by the quality group pertained to all drugs, all products that were manufactured.

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Procedures are not product specific. Procedures tell you how to perform an operation.

BY MR. MILLER:

Q. They're not product specific, therefore, they apply to all products.

A. Procedures do not necessarily apply to a product.

Q. Okay. Well, my question is, you agree that Actavis had issues with their enforcement or use of GMP in the quality group in 2007.

MR. ANDERTON: Objection.

That's not your question and that mischaracterizes his testimony.
BY MR. MILLER:
Q. It's okay to answer.
A. Can you rephrase that for me?
Q. Certainly.
There were issues in the quality group of Actavis Totowa in 2007 regarding their use of GMP.
MR. ANDERTON: Objection.
BY MR. MILLER:
Q. It's okay to answer.
MR. ANDERTON: You may answer.
THE WITNESS: True. But I'm going to ask you, what do you mean by issues specifically?
BY MR. MILLER:
Q. Well, is -- are lab notebooks that do not include all raw test data generated during testing, something like that, an issue?
MR. ANDERTON: Objection.
You may answer.
THE WITNESS: Potentially, that may

be an issue. That is true.
BY MR. MILLER:
Q. Potentially, and if the FDA had a finding such as that and put it in a warning letter, more likely than not, it's an issue.
MR. ANDERTON: Objection.
You may answer.
THE WITNESS: Not necessarily. Depending on the company's response.
BY MR. MILLER:
Q. Did GMP issues ultimately result in the shutdown of production of all products in August 2008 at Actavis Totowa?
MR. ANDERTON: Objection.
You may answer.
Actually, wait. I instruct you to answer only with respect to Digitek.
THE WITNESS: With respect to Digitek, yes.
BY MR. MILLER:
Q. I'm going to hand you what I'm going to mark as Exhibit 55.
MR. ANDERTON: Thank you.

Q. For the recall.
A. No. In -- I would say, in their normal -- they might have helped out for the recall, but nothing beyond their normal duties, because there was a recall coordinator who was taking care of the recall.
Q. Who was the recall coordinator?
A. Initially, I can remember that Misbah Sherwani was preparing the recall packages.
Q. I'm sorry. What was the name?
A. Misbah Sherwani.
MR. ANDERTON: I'm going to instruct you to answer only with respect to Digitek.
THE WITNESS: With respect to Digitek.
MR. ANDERTON: Okay.
BY MR. MILLER:
Q. And then when did the recall coordinator change from Misbah to the next person?
A. I believe that Misbah Sherwani

system in 2007 or did you have someone in your staff or anyone go back and enter data from previous years?

A. I remember that I started the spreadsheet in 2007. I cannot confirm today if they went back.

They might have, but I'm not 100 percent sure two years later if we did actually go back and incorporate data from -- from earlier years.

Q. Does your Access software, the screen, does it have a name, like enter the "blank" system?

A. I think it was called complaints database.

Q. Okay. A good name.

Is that still what it's called today?

A. I do not know if that database is still in use today.

Q. Was it picked up and used by other entities, besides Actavis Totowa?

As a part of your harmonization, did you get other --

A. No.
Q. -- plants to use it?
A. No, it was not.
Q. Last question on it: As you sit here today, you feel certain that you could go back to it now and the data that you entered would still be there today?
MR. ANDERTON: Objection.
You may answer.
THE WITNESS: The reason why we kept physical logs is to avoid having to do what you just said, because the physical log is -- is not going to be obliterated in this case.
With Excel sheets, you need to validate those appropriately, otherwise, they're not FDA accepted.
BY MR. MILLER:
Q. Okay. My question is, you don't have any reason to believe that the database and the spreadsheets don't exist now.
A. No.
Q. Okay.
A. But I do not know. I do not have a reason to, but I do not know.

have been a way for me to know, okay, this is the one that I want to send out with this particular format, because the document would evolve as you're preparing it.

Q. Okay. And in May of 2007, this is something that would have been part of your visit prior to beginning employment at Actavis Totowa.

A. That is correct.

Q. Okay. And so, and this would -- meeting, as you stated earlier, was more of a harmonization aspect than an assessment?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: True.

BY MR. MILLER:

Q. Okay. Do you recall Mr. Talbot -- did Mr. Talbot request from you that you put together an investigation log or was an investigation log a typical document that was produced in the ordinary work that you were doing?

A. Okay.

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: As previously explained, most of the logs are kept manually. Okay. So it's a book and you have whether it's a complaint, an investigation. It is a manual log.

In this case, again, the spreadsheet was being prepared to make it easier to look at data.

BY MR. MILLER:

Q. Oh, okay. Well, I think you just clarified it for me.

I was going down the road that this was an investigation of something going on in the lab at Actavis. Okay. So this pertains not to that. It pertains to complaints from customers.

A. No. This is an investigation log. It's not a complaint log. But it's a similar log to one you would create for complaints.

Q. So it is, then -- it's a QA, QC

lab type investigation. This is not a customer complaint issue at all; correct?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: No. This is not a customer complaint.

BY MR. MILLER:

Q. Right.

A. This is a log containing all the investigations that would be issued internally to -- to check events that might occur during the course of manufacturing or testing or whatever.

Q. Okay. So, by way of example, if you had an out-of-spec finding in the lab, that would be an investigation?

A. Not necessarily. Investigation -- out of specs are sometimes put in separate logs, depending on which system you use. An out of -- an out of spec can become at a later stage an investigation.

So from this title, I cannot tell you that out of specs were in that particular log.

Q. Was there any type of Access database or any other system that was used to track the -- which investigations were open or closed?

A. I think the -- the manual log and potentially this Excel spreadsheet, if I could exactly know what's in it, would be the logs that would be used to track open or closed.

But the official book would be the manual logbook, at least at this stage.

Q. And who maintains that manual logbook?

A. That manual logbook was maintained by the QA director.

Q. Okay. So the entries into the Excel spreadsheet would have been done in a different department than yours and you're just forwarding on a copy of an Excel spreadsheet that you received from the other department.

A. My belief is that my -- that here I was just creating a spreadsheet for them to be able to populate with -- with

you joined the company in October of 2007?

A. No. I do not believe it was held similarly to -- to what is written here.

Q. Well, explain that. Did they have Quality Review Board meetings in 2008?

A. Towards late 2008, I believe, we started having Quality Review Boards.

Q. What was the impetus? What started the Quality Review Board?

A. Our --

MR. ANDERTON: Objection.

You may answer.

BY MR. MILLER:

Q. It's okay to answer if you know.

A. Part of the harmonization project, as I was explaining before, was to get all sites, you know, to operate in the same way.

And one of the -- one of the aspects of the corporate manual is having a Quality Review Board in place, which is carried

out once a month.

Q. So, going back, dating back to when you were looking at the company and trying to make it function or harmonized much like the other companies, or to get everyone in the same step, I guess, was it your -- was it your recommendation that a QRB board meeting be held every month?

A. I cannot recollect that was one of my recommendations because they did hold meetings, maybe under a different format, but they held meetings.

Q. So before it was titled the Quality Review Board, there were, in fact, some type of quality meeting going on every month?

A. Yes, they would have meetings.

Q. And were there minutes to those meetings?

A. I cannot attest to that, if they had minutes or not at that point in time.

Q. All right. And then your E-mail to Tony, you've attached the

minutes from the particular meeting, the one prior to February 2nd of 2009.

Was it your job to keep the minutes?

A. Yes.

Q. Okay. And how did you do that?

Did you take notes during the meeting or did someone take notes for you?

A. I would take notes during the meeting.

Q. What does CAPA stand for?

A. CAPA is a term used in our industry and it's called Corrective Action/Preventative Action.

Q. And was there a CAPA team?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: At which point in time?

BY MR. MILLER:

Q. We'll start with October of 2007, when you arrived.

A. Yes, there was a CAPA team.

Q. And was that CAPA team a result

of your assessment in 2007?

MR. ANDERTON: Objection.

I instruct the witness not to answer.

BY MR. MILLER:

Q. Was the focus of the CAPA team in 2007 to address GMP issues?

A. In general, CAPA is always to address GMP issues.

Q. Okay. Was the CAPA -- what was the focus, then, of the CAPA team in October of 2007?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: CAPA is used to look at areas which need a potential improvement or as a result of -- of an internal investigation, and the focus would be to make those improvements.

BY MR. MILLER:

Q. And when you were a member of the CAPA team, back in 2007, did you have any weekly or monthly meetings?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: I believe we had meetings. I cannot recall specifically if they were weekly, fortnightly or monthly.

BY MR. MILLER:

Q. I don't mean --

A. I would -- I would say monthly meetings would be typically what you would have.

Q. Were minutes kept at those?

A. I cannot say that formal minutes, like the ones you have here, would be kept.

Q. Did you maintain notes from your CAPA meetings?

A. I cannot say or I cannot recollect whether it was me or one of my team or --

Q. Or someone --

A. Or if it was done alternatively. Someone might have kept points, but not specifically minutes like you have here.

Q. I'm going to hand you what's

practices?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: There's a long list.

BY MR. BLIZZARD:

Q. Okay. I'm not asking you to list them. I'm asking you to generally describe so that the jury understands what they are. What are good manufacturing practices?

A. Okay. They're a set of rules and guidances which direct you in the manufacturing and packaging and testing of your product.

Q. And what is the purpose of these rules and guidances?

MR. ANDERTON: Objection; asked and answered.

You may answer.

THE WITNESS: The objective is to manufacture a tablet which is good for human use.

BY MR. BLIZZARD:

Q. Okay. So is it part of the

good manufacturing practices to assure safety?

A. Yes.

Q. Is it also part of good manufacturing practices to assure that the pills have the appropriate identity, strength and quality and purity?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Yes.

BY MR. BLIZZARD:

Q. Is it the standard of care within the manufacturing of pharmaceuticals industry to follow good manufacturing practices?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Yes.

BY MR. BLIZZARD:

Q. And if a company fails to follow good manufacturing practices, is it in violation of the standard of care?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Yes.

BY MR. BLIZZARD:

Q. Now, you've also mentioned another term earlier today called SOPs, and we use that a lot as shorthand, and I want to make sure the jury understands what an SOP is.

So could you explain what an SOP is?

A. It's a standard operating procedure.

Q. And what are standard operating procedures?

A. They are documents which describe how you do something --

Q. Okay.

A. -- in a step-by-step way.

Q. And are standard operating procedures the company's own rules about how the work should be done?

A. Can you repeat the question?

Q. Yes.

Are standard operating procedures the company's own internal rules about how

manufacturing, quality control and quality-assurance work should be done?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: They are not the company's own rules. They are based on GMPs.

BY MR. BLIZZARD:

Q. Okay. So there are GMPs which are external rules of the FDA; correct?

A. Yes.

Q. And those sort of set the standards for how pharmaceutical companies should operate; correct?

A. Yes.

Q. And then the company adopts standard operating procedures that are consistent with the good manufacturing practices that are those FDA rules; correct?

A. Yes.

Q. Okay. And should the company violate either their own standard operating procedures or good manufacturing practices?

MR. ANDERTON: Objection.
You may answer.
THE WITNESS: What is -- that is not a question.
BY MR. BLIZZARD:
Q. Yeah. I said, the question is, should a company violate good manufacturing practices or its own SOPs?
MR. ANDERTON: Objection.
You may answer.
THE WITNESS: No.
BY MR. BLIZZARD:
Q. Okay. Is it unreasonable or imprudent for a pharmaceutical company to violate their own standard operating procedures and their -- and the good manufacturing practices?
MR. ANDERTON: Objection.
You may answer.
THE WITNESS: Yes.
BY MR. BLIZZARD:
Q. Are there potential health risks that can be created if a pharmaceutical company does not follow

good manufacturing practices?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: It depends.

BY MR. BLIZZARD:

Q. Okay. What does it depend on?

A. It depends on where they do not follow good manufacturing practices.

Q. Okay. If a product is out of spec, can that create a health risk?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: It depends what -- what the out of spec is for.

BY MR. BLIZZARD:

Q. Okay. How about if it's for a pharmaceutical product that has a narrow toxicity window?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Again, it depends what the particular OS is for.

BY MR. BLIZZARD:

Q. Okay. Do you know what Digitek

Q. I'm going to show you what I'm going to mark as the next exhibit, if I can find the exhibit stickers.

Before I do that, do you know what the QSIP is?

A. Yes.

Q. And is -- were you involved in the QSIP for Actavis Totowa?

A. At what time?

Q. At any time.

A. Right now, yes, I am.

Q. Okay. And does QSIP stand for Quality System Improvement Plan?

A. Yes.

Q. And was the Quality System Improvement Plan initiated as a result of an inspection by the FDA in 2006?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: I do not know that.

BY MR. BLIZZARD:

Q. Do you know whether the Actavis Totowa committed in 2006 to the FDA, following an inspection of the plant, that

full-time employee of Actavis Totowa in October of 2007; correct?

A. Yes.

Q. Before that you were employed by a separate corporation called Actavis, Limited; correct?

A. Yes.

Q. And it was only after October of 2007 that you came indirectly involved with the Quality Systems Improvement Plan; correct?

A. Yes.

Q. And what was your indirect involvement?

A. The Quality Systems Improvement Plan as it stands is to create actions for improvement or -- or tasks. So I was given tasks on occasion which my department had to fulfill.

Q. Have you ever heard of the phrase "if it ain't broke, don't fix it"?

A. In America, I've heard that.

Q. Okay. So was there -- was the quality system broken before this Quality

System Improvement Plan was instituted?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: I cannot say that.

BY MR. BLIZZARD:

Q. Let me hand you what I'm going to mark as Exhibit 67 to your deposition.

MR. BLIZZARD: I'm sorry. I did mark it as 67, but I'm going to re-mark it.

MR. ANDERTON: Exhibit 64. Is there an exhibit goblin here today?

MR. BLIZZARD: There's always an exhibit goblin when I'm involved.

(Exhibit 64 was marked for identification.)

BY MR. BLIZZARD:

Q. Okay. This exhibit as goblined has got real tiny print.

A. Uh-huh.

Q. So I'm going to see if I can enlarge it.

Okay. Do you see -- do you know what this document is?

A. It looks like an extract from

another document.

Q. Okay. Do you see, at the top, it says, "Actavis, status of QSIP deliverables"?

A. Yes.

Q. And is QSI deliverable, does that stand for the Quality System Improvement Plan?

A. Yes.

Q. Now, you said you think this is an excerpt from another document? Or what did you say about it?

A. At the bottom I see Page 31 of 74.

Q. Okay.

A. That's why I say that.

Q. Yeah. We picked out the pages that had your name on it so --

A. Okay.

Q. -- that's what I'm going to show you.

Does it show that you've been assigned some deliverables here for the QSIP?

A. Yes.

Q. Okay. And is there a date out to the margin, date open?
A. Yes.
Q. Do you see the date open was 11/6/06?
A. Yes.
Q. Do you see that the task is, "Evaluate effectiveness and efficiency of changes"?
Do you see that?
A. Yes.
Q. Do you see that you're listed as the responsible party for that?
A. Yes.
Q. Are you the responsible party for that?
A. Yes.
Q. What have you done to evaluate the effectiveness and efficiency of changes?
A. I looked at the procedures that they had in place.
Q. Okay. When did you do that?
A. I did that around about

initially when I started. That was one of the first things I was looking at.

Q. Would that have been October of 2007?

A. Around about.

Q. Okay. Well, it says this was opened in November of '06, doesn't it?

A. That's correct.

Q. Do you know if anybody was assigned this task before you?

A. No.

Q. Okay. So the task was opened in November of '06, but you didn't start working on that until October of '07?

A. That is correct.

Q. Was there nobody else in the company that could have done this?

MR. ANDERTON: Objection.

THE WITNESS: I cannot answer to that.

BY MR. BLIZZARD:

Q. Well, you think a year's delay in doing this kind of work is appropriate?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: No. Because this is an evaluation of the effectiveness of the current system.

BY MR. BLIZZARD:

Q. Right.

And, actually, this plan, the Quality System Improvement Plan, assuming it was a commitment to the FDA in 2006, it should be attacked pretty quickly, shouldn't it?

MR. ANDERTON: Objection.

THE WITNESS: I cannot reply to that because I wasn't there at that time.

BY MR. BLIZZARD:

Q. Okay. Did anybody tell you that this QSIP, which you were given some assignments from, was something that was part of a commitment to the Food and Drug Administration here in the United States?

A. Yes.

Q. Who told you that?

A. Scott Talbot.

Q. Okay. When did he tell you that?

A. I do not remember the exact date.

Q. Okay. Did you do any of this work during your prior visits to the United States?

A. My prior visits, as was initially said, was to assess and down the line to harmonize. So some of this work might have actually been done prior to this date, but not under this umbrella.

Q. Okay. So it was work that you would have done under the umbrella of Actavis, Limited; correct?

A. No, that is not correct.

Q. Okay. So you're saying you didn't do any work on the QSIP or any of these deliverables for the QSIP until you actually went to work for Actavis Totowa; is that correct?

A. Yes. Because I was not a direct employee at the time.

Q. Okay. So the first work you could have ever done on any of these assignments under the QSIP would have been

Q. Right.

But it means the same thing as a corrective action plan; correct?

A. Yes.

Q. And both a corrective action plan and a quality -- Quality Systems Improvement Plan, both are intended to address deficiencies in the quality department, are they not?

A. No, that is not correct.

Q. Okay. They're both intended to address deficiencies in the company; correct?

MR. ANDERTON: Objection.

THE WITNESS: That is not correct.

BY MR. BLIZZARD:

Q. Okay. So are corrective action plans part of the routine business of the company?

A. Yes.

Q. And is it also a routine part of the company business to do assessments of the company's compliance with GMPs?

A. Yes.

Q. And when you do an assessment of the company's compliance with GMPs, you're not necessarily being critical of every aspect of the company's operations, are you?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: That is correct.

BY MR. BLIZZARD:

Q. So the assessment is just objectively going in and trying to document whether or not there's compliance or not compliance; correct?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Depends on the type of assessment you're making.

BY MR. BLIZZARD:

Q. Okay. The kind of assessments you were making, was that a fact-based assessment?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: What do you mean by a

single S, I'm not sure, O-N.

Q. Okay. You're on to the next round of the spelling bee.

So this report that you sent to the QSD department, the quality systems department, was it the assessment that is referenced here on this document?

A. In respect to 13.1?

Q. Yes. Was that part of the assessment?

A. Part of it would have been there.

Q. Yes.

And if you look a couple spaces down, is there another listing of an assessment and mod complaint system?

Do you see that?

A. One second. Yes.

Q. Was that part of the report that you sent to the QSD?

MR. ANDERTON: Objection.

I'm going to instruct the witness not to answer.

MR. BLIZZARD: Okay.

to work as an employee of Actavis Totowa?

A. Afterwards.

Q. Okay. Did anybody do this work before you became a full-time employee of Actavis Totowa, as far as you know?

A. I do not know that.

Q. Okay. So is this another example of the task being opened in November of '06 and work not being done on it until about a year later?

MR. ANDERTON: Objection.

THE WITNESS: I --

MR. ANDERTON: Mischaracterizes his testimony.

You may answer.

THE WITNESS: I cannot say that. I can say that I started to work at a later date when I was coming over.

BY MR. BLIZZARD:

Q. Okay. Well, what I understood you to say is, you didn't start on it until October of '07; correct?

A. Under the QSIP umbrella, that is correct.

Q. And as far as you know, nobody else started working on it before that date; correct?

MR. ANDERTON: Objection. That is not what he said. Mischaracterizes his testimony.

BY MR. BLIZZARD:

Q. Do you know of anybody who did this work before you?

A. There was a person in charge of compliance, and that person was Leroy Lundner, but I do not know the specifics of his job.

Q. Okay. Well, this item says, review compliance status of existing vendors. Do you know whether Mr. --

A. Excuse me.

Q. I'm sorry.

Do you know whether Mr. Lundner did that before you started working, reviewed the compliance status of existing vendors?

A. I do not know that.

Q. Okay. And then the next item assigned to you on this page, does it say,

"Develop change control metrics"?
A. Yes.
Q. And that item was actually opened on December 13 of '06; correct?
A. Yes.
Q. Did you -- were you assigned that task at that time?
A. No.
Q. When were you assigned the task?
A. After I started in October '07.
Q. All right. Do you know of anybody else who did that work before you started in October of '07?
A. I cannot answer that question because I do not know.
Q. Now I'm going to mark Exhibit 67 to your deposition.
(Exhibit 67 was marked for identification.)
MR. ANDERTON: Thank you.
BY MR. BLIZZARD:
Q. Is this another page similar to the ones that we've seen before?

know what this task -- are you familiar with the task?

A. No.

Q. Doesn't ring any bells with you?

A. No.

Q. Do you know what an open critical CAPA communication is?

A. Yes.

Q. What is it?

A. It is communicating any CAPAs that are critical which have not been completed.

Q. Okay. So this assignment, as described, would have you distribute critical CAPAs that hadn't already been distributed; correct?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Incorrect.

BY MR. BLIZZARD:

Q. Okay.

A. Completed.

Q. Okay. Distribute those that

observation?

A. Yes.

Q. Would that reflect a violation of GMPs?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: As written by the inspector, potentially, it could. Again, I do not see the response from the company, so I do not know if this is actually true.

BY MR. BLIZZARD:

Q. Okay. Look at Observation Number 3 on the second page.

Do you see where it says, "The responsibilities and procedures applicable to the quality control unit are not fully followed"?

Do you see that?

A. Yes.

Q. Would that be a violation of good manufacturing practices?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: As written,

potentially, it could. I do not see the -- the response from the company, so I cannot say that this statement is true or not.

BY MR. BLIZZARD:

Q. Okay. Let's look at the Observation Number 4.

Do you see where it says, "Written records are not always made of investigations into the failure of a batch or any of its components to meet specifications"?

Do you see that?

A. Yes.

Q. Would that be a violation of GMPs?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: As written by an inspector, potentially, yes. But, again, I do not have the response from the company, so I cannot make any comments to that.

BY MR. BLIZZARD:

Q. Okay. And would the same hold true for the remaining observations here in this document?

MR. ANDERTON: Objection.
BY MR. BLIZZARD:
Q. That is, you would give the same answer that these are violations of GMPs subject to what the company says about it.
MR. ANDERTON: Objection.
I'm not going to allow him to testify about stuff that's not in the record.
MR. BLIZZARD: Okay.
BY MR. BLIZZARD:
Q. Let's go to Observation Number 5 then. It says, "Input to and output from the computer are not checked for accuracy."
Would that be a violation of GMPs?
MR. ANDERTON: Objection.
You may answer.
THE WITNESS: As written, potentially, yes. I do not have a response, so I cannot make any comments.
BY MR. BLIZZARD:
Q. Okay. If you look at Observation Number 6, do you see where it

says, "The suitability of all testing methods is not verified under actual conditions of use"?

Would that be a violation of GMPs?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Potentially, yes, as written. I do not have a response from the company, so I cannot make any comments to that.

BY MR. BLIZZARD:

Q. Look at Observation Number 7.

Do you see where it says, "The written stability testing program is not followed"?

Would that be a violation of GMPs?

A. Potentially, yes, as written. However, again, there's no response which I can look at, so I cannot make any comments.

Q. As written, this reflects pretty shoddy work by the company, doesn't it?

MR. ANDERTON: Objection.

If you understand whether there's a

question there, you may answer.

THE WITNESS: What is the exact question?

BY MR. BLIZZARD:

Q. Do you know what the word "shoddy" means?

A. Yeah.

Q. So somebody who's worked in quality for years, would you say that the descriptions here of the company's behavior reflects shoddy work?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: The inspector, as he has written these observations, is looking at potential issues. However, these are not substantiated by a response from the company, so I cannot say if it's shoddy work or not.

(Exhibit 69 was marked for identification.)

BY MR. BLIZZARD:

Q. Let me show you what I'm going to mark as Exhibit Number 69 to your deposition.

FDA documents that relates to a product other than Digitek, just so that it's in the record.

MR. BLIZZARD: Okay.

THE WITNESS: Okay.

BY MR. BLIZZARD:

Q. Would this observation be a violation of good manufacturing practices?

A. As written, potentially, yes. Without seeing the response to see if this is completely true or correct, I cannot make any assumptions.

Q. Okay. Well, were you ever told what the company's response was to this?

A. Yes. But I do not remember the content of the response.

Q. Do you know whether the company disagreed with the finding?

A. As I said, I do not remember the content of that response.

Q. How about Observation Number 2 where it says, "drug products failing to meet established specifications and quality control criteria are not rejected"; would that be a violation of

GMPs?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: As written, yes, potentially. But, again, I need the response to see what exactly is the truth in the statement.

BY MR. BLIZZARD:

Q. What happened -- what did the company do after this FDA inspection?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: The company did a voluntary recall of all its products.

BY MR. BLIZZARD:

Q. Okay. Well, would that indicate to you that the company was in agreement with the observations made by FDA?

MR. ANDERTON: Objection.

THE WITNESS: I cannot answer for the company or for who took that decision.

BY MR. BLIZZARD:

Q. Okay. Well, I mean, the FDA made these findings, and following that,

the company voluntarily recalled all of its products; correct?

A. That is correct.

Q. Would you agree with me that that signals, at least somewhat, that the company agreed with the FDA's assessment?

MR. ANDERTON: Objection; asked and answered.

You may answer.

THE WITNESS: To me, it would appear that the company is being responsible in ensuring that its products are not on the market in view of this response.

I cannot say that -- I do not know why they took that decision because I wasn't part of that decision.

BY MR. BLIZZARD:

Q. Were you ever at a meeting where there was a presentation about these very issues?

A. I do not remember.

MR. BLIZZARD: Is the next Exhibit Number 70, I believe?

(Exhibit 70 was marked for

A. Out of specification.
Q. Okay. So this commitment to recall multiple batches of 18 product codes occurred before the recall of Digitek; correct?
MR. ANDERTON: Objection.
You may answer, if you know.
THE WITNESS: I cannot -- I cannot answer that.
BY MR. BLIZZARD:
Q. Okay. Look over to the next page. Do you see that there's a date of April 23rd, 2008, there?
A. Yes.
Q. Do you see the third bullet point says, "Decision was made to suspend the manufacturing & distribution of all products manufactured at Actavis Totowa"? Correct?
A. That's what's written.
Q. Okay. Then also there's a -- looks like a name is blacked out. I think that name is PAREXEL "was retained by counsel to perform assessments of each

product as a precondition to the resumption of manufacturing and distributing it."

Do you know whether PAREXEL has done any such work on Digitek?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: I do not know.

BY MR. BLIZZARD:

Q. Do you see where it says, "On April 24, 2008, at the direction of Counsel," blacked out, "started product and system assessments"?

Do you know whether any third party, such as PAREXEL, did any product and system assessments on Digitek?

A. I do not know.

Q. So this has a date -- this page has a date of April 23, 2008; correct?

A. Yes.

Q. And, according to this page, a decision was made on that date to suspend the manufacture of all products; correct?

MR. ANDERTON: Objection;

mischaracterizes the document.

You may answer.

BY MR. BLIZZARD:

Q. Isn't that what it says?

It says, "Decision was made to suspend the manufacture & distribution of all products manufactured at Actavis Totowa"; correct?

MR. ANDERTON: Objection. Doesn't indicate -- well, mischaracterizes the document.

You may answer.

THE WITNESS: I'm not seeing a date.

BY MR. BLIZZARD:

Q. Okay. It's the fourth bullet. Do you see where it says --

A. Yes.

Q. Up at the top there's a date of April 23rd, 2008, isn't there?

A. At the top of the --

Q. Yes.

A. -- page, yes.

Q. Okay. And does it say, under that fourth bullet, "decision was made to

suspend the manufacture & distribution of all products manufactured at Actavis Totowa"?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Yes. Without specifying a date.

(Exhibit 71 was marked for identification.)

BY MR. BLIZZARD:

Q. Take a look at Exhibit 71. Does this appear to be another time line of Actavis Totowa?

Is that what this appears to be, a time line relating to the issues we've just been discussing?

A. Yes.

Q. Okay. Do you see this date here, April 23rd?

Do you see that?

A. The one on top, yeah.

Q. Yes.

The start date is March 18th, start of FDA inspection of Riverview.

to recall all lots of Digoxin."

Do you see that?

A. Yes.

Q. "Suspended production at Little Falls."

Do you see that?

A. Yes.

Q. Were you involved in any of these meetings?

A. No.

Q. Were you involved in any of these decisions?

A. No.

Q. Has anybody to this day communicated anything about these decisions to you?

A. Specifically? Can you rephrase the question?

Q. Yeah. Okay.

Has anybody communicated to you about why they shut down the plant and recalled all the products made at the plant?

MR. ANDERTON: Objection.

I'm going to instruct the witness

to answer only with respect to Digitek.

THE WITNESS: With respect to Digitek, it was in view of the findings that the FDA found.

BY MR. BLIZZARD:

Q. Well, they suspended operations at the entire plant, didn't they?

A. Yes.

Q. Do you know why?

MR. ANDERTON: Objection.

THE WITNESS: I believe they wanted to ensure that they could address the findings from the FDA before resuming any manufacturing.

BY MR. BLIZZARD:

Q. Of any drug; correct?

A. If that was with respect to any drug, I cannot say that that decision was made because I wasn't there.

Q. Okay.

A. The outcome is pretty clear.

Q. Okay. Because of the findings of the FDA, and the involvement in -- of senior management in the discussion with FDA, was it uncertain whether the drugs

being produced by the plant, any of them, were in compliance with GMPs?

MR. ANDERTON: Objection.

I instruct the witness to answer only with respect to Digitek.

THE WITNESS: I do not know if -- if there was a -- if they were uncertain or not. I did not make that decision.

BY MR. BLIZZARD:

Q. Okay. Do you know whether Digitek was produced in accordance with GMPs?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: I was not directly involved in the manufacture or release of Digitek.

BY MR. BLIZZARD:

Q. Okay. Well, from the work that you did, as your job in quality, and the from the assessments you did back in 2007, can you testify under oath that the Digitek that was sold in 2007 and 2008 was in compliance with good manufacturing

practices?

MR. ANDERTON: Objection.

He's just testified he didn't have anything to do with it.

THE WITNESS: I neither --

MR. BLIZZARD: That's not a legal objection. Please don't make speeches.

THE WITNESS: I neither manufactured nor released those products and my function was strictly documentation, change control and complaints.

BY MR. BLIZZARD:

Q. Okay. Well, you were making just overall assessments, then, of whether the company was in compliance with GMPs; correct?

A. I was sent there to make an assessment.

Q. Okay. And from the assessment you made overall, could you testify under oath that any drug for sure went out of that plant having been manufactured according to GMP?

MR. ANDERTON: Objection.

I instruct the witness to answer only with respect to Digitek.

THE WITNESS: Again, being the person who is not really -- who does not release the product, I do not see those documents and, hence, I cannot say that they were or were not in accordance to GMP.

BY MR. BLIZZARD:

Q. Okay. Who were the -- who is the person I should ask that question to?

A. Okay. The person who releases the product at that point in time was Dan Bitler.

Q. Okay. So Mr. Bitler is the person who we should ask the question, was Digitek made in accordance with GMPs; correct?

A. I -- I cannot answer that question. That's not up to me to state who you question or -- or what.

Q. Is he, as far as you know, the person with most knowledge of that subject?

MR. ANDERTON: Objection.

minute. You know it's time to end. So -- or maybe we should say, in a second we'll substitute the minutes.

But, in any event, this refers to a Quality Review Board being formed. This document here that's dated or has this May 21, 2008, date at the top; correct?

A. Yes.

Q. Are you a member of the Quality Review Board?

A. Yes.

Q. And what does the Quality Review Board do?

A. The Quality Review Board is a group of people from different disciplines or different departments and the objective of the Quality Review Board is to look at the various metrics that the company produces.

Q. You said metrics?

A. Yes.

Q. Meaning what?

A. Numbers in general, you look at change control, investigation, batches

produced, batches released, new filed products, complaints, annual product reviews.

Q. Okay.

A. It's a number of --

Q. So is this looking at actual data from the organization -- quality part of the organization to determine the relative health of that organization?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: You're not looking at actual data. You're looking at numbers extracted from actual data.

BY MR. BLIZZARD:

Q. Okay.

A. To show graphs or whatever.

Q. Right.

So you might show a graph of how many investigations have been closed over certain periods of time, et cetera; correct?

A. Yes, that is correct.

Q. Now, how often does the Quality Review Board meet?

A. Once a month.
Q. And who else is on it?
A. We have quality, manufacturing, packaging, regulatory affairs, compliance, and various other groups who may come in occasionally.
Q. Okay. But the regular members are those that you just mentioned?
A. More or less, I would say yes, they are the regular members.
Q. And are you the representative of quality on the board?
A. I am one of the representatives of quality on the board.
Q. Who else is on the board from the quality group?
A. The head of QC. The head of New Jersey quality, Mr. Tony Delicato is on that board, and the QA director, Ms. Lynn Kelleher, is on that board.
Q. Okay. Who's the head of QC?
A. Currently, the person who is managing the lab is Mr. Jisheng Zhu.
Q. That's Z-H-U?

A. Yes, that is correct.
Q. And are there regular minutes kept of these board meetings?
A. Yes, there are.

MR. BLIZZARD: I don't have any additional questions.

But I do -- to the extent I need to say it, I'm not sure I do, but I'll reserve the right to come back and to ask additional questions depending upon the rulings on the -- of the Court on the instructions that have been given to the witness.

VIDEO OPERATOR: Off the record, 4:22.

(Discussion off the record.)

VIDEO OPERATOR: Back on the record, 4:24.

EXAMINATION

BY MR. MILLER:

Q. Only a few questions and we'll wrap this up.

I'm going to revisit some exhibits from earlier today that were previously marked as OCRs, I believe, I'm learning about this, but

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before completion of the deposition that the witness, PAUL GALEA, have the opportunity to read and sign the deposition transcript.

ROSEMARY LOCKLEAR
REGISTERED PROFESSIONAL REPORTER
CERTIFIED COURT REPORTER (NJ)
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Dated: 12/23/09

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Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the Errata Sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

ACKNOWLEDGEMENT OF DEPONENT

I, _____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

PAUL GALEA DATE

Subscribed and sworn
to before me this
_____day of _____, 20_____.

My commission expires:_____

_____
Notary Public